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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,884	08/10/2001	Gary Van Nest	377882001720	5141

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,884

Applicant(s)

VAN NEST ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 14, 16-63, 69 and 71-80 is/are pending in the application.
- 4a) Of the above claim(s) 30-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-8, 14, 16-23, 25-29, 56-63, 69, 71-80 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

Applicants amendment filed March 15, 2004 has been received and entered. Claims 9-13, 15, 64-68, and 70 have been canceled and new claim 80 has been added. Consequently claims 1-8, 14, 16-63, 69, 71-80 are pending in the instant application, of which claims 30-55 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-8, 14, 16-23, 25-29, 56-63, 69, and 71-79 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained. Additionally this rejection is applied to newly added claim 80.

It is noted that this rejection has been withdrawn from claim 24 in view of the claim language reciting "consisting of" a sequence...

Applicants are asserting that the common attribute or characteristic concisely identifying members of the genus of IMP/MC of the claimed invention is that the ISS (or polynucleotide) of the complex includes the sequence 5'-C-G-3'. Applicants further assert that the ISS of the invention "can be any length greater than 6 bases or base pairs and generally comprises the sequence 5' cytosine, guanine 3'" (for example, at

page 19, lines 30-31). Applicants conclude that the sequence 5' C-G-3' is an essential feature of any IMP/MC of the claimed invention.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are assert that the common attribute or characteristic concisely identifying members of the genus of IMP/MC of the claimed invention is that the ISS (or polynucleotide) of the complex includes the sequence 5'-C-G-3'. However, Applicants "structural requirements" are so minimal as to not enable one of skill in the art to identify members of the genus. For instance, the human genome comprises approximately 2,900,000,000 nucleotides. The entire 2.9 billion nucleotides consist of only 4 nucleotides, (i.e., G, C, A, & T). Given that Applicants claims do not recite the length of the ISS sequence, or the amount of space permitted between the 5' C and the G' 3, each and every DNA encoding gene in the entire genome will be encompassed by this claim. Clearly, one of skill would still not be able to identify members of the genus, as no members appear to be excluded.

Second, Applicants further assert that the ISS of the invention "can be any length greater than 6 bases or base pairs and generally comprises the sequence 5' cytosine, guanine 3'." However, as set forth above, this still encompasses every gene in the human genome, and every gene in every other organism's genome as well.

Finally, Applicants conclude that the sequence 5' C-G-3' is an essential feature of any IMP/MC of the claimed invention. However, the question remains if every gene contains the nucleotides C and G, how can this be an essential feature? One of skill in

the art would simply be unable to identify the members of the genus based upon this bare bones structural requirement.

Claims 1-8, 14, 16-23, 25-29, 56-63, 69, and 71-79 recite a immunomodulatory polynucleotide/microcarrier comprising an immunostimulatory sequence (ISS) linked to a nonbiodegradable microcarrier (MC), wherein the ISS comprises the sequence 5' C, G 3'.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a "modified gene" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

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he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claim 56 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of the phrase "optionally" is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 20 and 26 under 35 U.S.C. 102(b) as being anticipated by Uhlen is maintained.

It is noted that this rejection is withdrawn against the remaining claims in view of the amendment to recite nucleotide sequences TCGAAAA, TCGCCCC, TCGGGGG, TCGTTTT, and TCGTCGX.

Applicants are asserting that Uhlen does not describe the polynucleotides as claimed nor the use of the complexes for immunomodulation of an individual. Applicants further assert that Uhlen does not teach of a sequence of TCGAAAA, TCGCCCC, TCGGGGG, TCGTTTT, and TCGTCGX. Applicants finally assert that Uhlen does not teach of a polynucleotide that is 7 nucleotides in length.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that Uhlen does not describe the polynucleotides as claimed nor the use of the complexes for immunomodulation of an individual. However the only structural requirements of the claim are a polynucleotide comprising the sequence 5'-C-G-3', linked to a nonbiodegradable microcarrier. Uhlen has described exactly such a molecule. (See Col 5, line 20 to Col. 9, line 12; and SEQ ID NO: 2, 4, and 14). Furthermore, Applicants assert that Uhlen does not teach the use of the complexes for immunomodulation, however Applicants are reminded that the intended use of a product carries no patentable weight. Given that the DNA-microcarrier complex is identical to the structure required by the claims, the disclosure of Uhlen is deemed to anticipate the claimed invention.

Second, Applicants further assert that Uhlen does not teach of a sequence of TCGAAAA, TCGCCCC, TCGGGGG, TCGTTTT, and TCGTCGX. However, Applicants are respectfully directed to the rejected claims. None of them recite these sequences, accordingly this argument is not persuasive.

Finally, Applicants assert that Uhlen does not teach of a polynucleotide that is 7 nucleotides in length. However, Applicants claims recite "comprising... 7 nucleotides in length." This open ended language allows for polynucleotides of 7 nucleotides up to and including positive infinity. Given that the sequence disclosed by Uhlen is longer than 7 nucleotides, the molecule disclosed by Uhlen is deemed to anticipate each and every limitation of the claims.

The claims are directed to a polynucleotide comprising an immunostimulatory sequence (ISS) linked to a nonbiodegradable microcarrier (MC), wherein the ISS comprises the sequence 5' C, G 3', wherein the polynucleotide is 7 nucleotides in length.

Ulhen (US Patent Number 5,629,158) disclose of an immunomodulatory polynucleotide/microcarrier complex, comprising an ISS comprising the sequence 5' C, G 3' covalently linked to the surface of a nonbiodegradable, solid phase microcarrier 25 nm and 5 micrometers in size. (See col. 5, line 20 to Col. 9, line 12; SEQ ID NO: 2, 4, and 14).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

4. The rejection of claims 1, 3, 56 and 58 under 35 U.S.C. 102(b) as being anticipated by Sonehara et al is withdrawn in view of Applicants amendment.

Double Patenting

5. Claims 1-29 and 56-79 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-11 and 56-66 of copending Application No. 09/802,376. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Claims 1-29 and 56-79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 56-66 of U.S.

Application No. 09/802,375. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses a polynucleotide immunostimulatory sequence linked to a nonbiodegradable microcarrier (MC), wherein the ISS comprises the sequence 5' C, G 3', with the proviso that if the MC is gold, latex or magnetic, the linkage is other than by biotin/avidin.

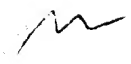
Claim 24 is objected to for depending upon a rejected base claim, however claim 24 is free of the prior art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
May 27, 2004